Blood sugar variations in daily life

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24370

Source
NTR

Brief title
Gluco-Pilot

Health condition

Health
Self-monitoring
Real-life
Glucose
Gezondheid
Zelf-meten
Real-life
Glucose

Sponsors and support

Primary sponsor: TKI Agri & Food
Nieuwe Kanaal 9-a
6709 PA Wageningen
Source(s) of monetary or material Support: Ministry of Economic Affairs
Wageningen UR, OME Health, Philips healthcare, FrieslandCampina, Jumbo, Noldus.

Intervention

Outcome measures

Primary outcome

The primary study parameters are:

- Daily food intake

- Daily glucose levels

- Wellbeing

- Activity patterns

- Sleep

Secondary outcome

The secondary outcomes are:
- Health/Lifestyle questionnaire at baseline

- Satiety questionnaire during and after the OGTT

- User experiences, after the study the user experience will be measured using a questionnaire. Overall, the questionnaire includes self-constructed scales that measure user experience with the research in general and self-monitoring devices

Study description

Background summary

Many people in the Western world have an unhealthy lifestyle, including an unhealthy dietary pattern. Numerous approaches have been taken to stimulate people to maintain a healthier diet, but results are highly variable across studies and subjects. One explanation for this is that in many approaches the individuals' specific needs and the context they live and work in are not sufficiently taken into account. For an approach to be more effective, personal characteristics need to be considered. In other words, the approach needs to be tailored or personalized. To provide personalized advice to an individual based on their glucose response and wellbeing in relation to food intake, the individual responses to food intakes must be known. At this point, real-world data on intra-individual variability in glucose responses to a specific food product is lacking.

Objective:

The primary goal is to obtain and investigate the added value of real-life high quality contextual data (e.g. food intake, physical activity, sleep, wellbeing) to understand and predict the fluctuations in individual glucose levels. The secondary objective is to define what metrics of glucose profiles can best be used to personalize lifestyle recommendations with respect to food intake and physical activity.

Study design:

This study is designed as an observational pilot study. For 14 days, the participants will wear a continuous glucose monitor (CGM) to self-monitor their glucose levels. Additionally, their activity patterns, heart rate and sleep quality and quantity are monitored. Furthermore, the participant is asked to register their food intake and score their wellbeing using a smartphone app.

Study population:

All 24 participants will be employed in the field of nutrition and health and will be selected from the Werkgroep Voedingsgewoonten (WeVo), Nederlandse Academie Voedingswetenschappen (NAV), and the Wageningen University (WUR).

Intervention:

In the first week of the pilot the participants are asked to perform an Oral Glucose Tolerance Test (OGTT). The participant is asked to fast for at least 10 hours before the OGTT drink is consumed. During the remaining days of the study, the participant can mostly follow their normal dietary pattern. Participants will be supplied with some standardized snacks, to improve comparability within and between participants.

Main study parameters/endpoints:

Primary endpoints are self-monitored daily food intake, glucose levels, wellbeing, physical activity and sleep patterns.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The risks associated with participation can be considered negligible and the burden can be considered minimal. Glucose levels will be measured for two weeks using a validated, commercially available minimally invasive glucose monitoring sensor. Benefits include that participants can get more insight in their individual health behavior and status by self-monitoring food intake, glucose levels, wellbeing and physical activity.

Study objective

The primary goal is to obtain and investigate the added value of real life high quality contextual data (e.g. food intake, physical activity, sleep, wellbeing) to understand and predict the fluctuations in individual glucose levels.

Study design

The study will last two weeks.

Physical activity, sleep and glucose will be measured continuously (CGM sensor and a Philips research device called ELAN sensor). Food intake will be assessed daily (self-reporting of all meals in a Smartphone application).

Well-being will be assessed four times per day via a Smartphone application (breakfast, lunch, afternoon, evening).

OGTT will be performed once in the first study week, combined with a satiety questionnaire. Lifestyle questionnaire will be filled out at baseline (t=0) and after two weeks. User experience questionnaire will be filled out after two weeks.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study a subject must be:

• A researcher in the field of nutrition or health

• Aged between 20 – 65

• In possession of a Smartphone running on iOS or Android.

• Able and willing to sign the informed consent form

• Willing to comply with all study procedures

Exclusion criteria

A potential subject who meats any of the following criteria will be excluded from participation in this study:

• Diabetes type 2 patients, and/or people with a finger-prick glucose value greater than 7.8 mmol/l during screening.

• BMI > 30

• Under treatment for neurological or psychiatric complaints, including eating disorders

• Coeliac disease or gluten intolerance

• Skin allergy, eczema or known sensitivity for plasters

• Skin irritation or wounds at the wrist
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• Performs intensive sport activities more than 6 hours per week

• Pregnant or lactating women
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Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-03-2019
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48507

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7117
NTR-old	NTR7322
CCMO	NL68969.028.19
OMON	NL-OMON48507

Study results

Summary results
n/a